

REQUEST FOR ACCESS OF ABANDONED APPLICATION UNDER 37 CFR 1.14(a)

PROCESSED BY
OCT 6 1997
FIU

In re Application of <u>Queen</u>	
Application Number <u>07/310,252</u>	Filed <u>2-13-89</u>
Group Art Unit	Examiner

Assistant Commissioner for Patents
Washington, DC 20231

Paper No. #17

I hereby request access under 37 CFR 1.14(a)(3)(iv) to the application file record of the above-identified ABANDONED application, which is: (CHECK ONE)

- ☒ (A) referred to in United States Patent Number 5585089, column _____
- ☐ (B) referred to in an application that is open to public inspection as set forth in 37 CFR 1.11, i.e., Application No. _____, filed _____, on page _____ of paper number _____
- ☐ (C) an application that claims the benefit of the filing date of an application that is open to public inspection, i.e., Application No. _____, filed _____, or
- ☐ (D) an application in which the applicant has filed an authorization to lay open the complete application to the public.

Please direct any correspondence concerning this request to the following address:

Betty Byrd
Signature
Betty Byrd
Typed or printed name

10-6-97
Date

FOR PTO USE ONLY

Approved by: [Signature]
(Initials)

Unit: All Information

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

United States Patent [19]

[11] Patent Number: 5,585,089
 [45] Date of Patent: Dec. 17, 1996

Queen et al.

[54] HUMANIZED IMMUNOGLOBULINS

[75] Inventors: Cary L. Queen, Los Altos; Harold E. Selick, Belmont, both of Calif.

[73] Assignee: Protein Design Labs, Inc., Mountain View, Calif.

[21] Appl. No.: 477,728

[22] Filed: Jun. 7, 1995

Related U.S. Application Data

[63] Continuation of Ser. No. 634,278, Dec. 19, 1990, Pat. No. 5,530,101, which is a continuation-in-part of Ser. No. 590,274, Sep. 28, 1990, abandoned, and Ser. No. 310,252, Feb. 13, 1989, abandoned, which is a continuation-in-part of Ser. No. 290,975, Dec. 28, 1988, abandoned.

[51] Int. Cl.⁶ C07K 16/18; A61K 39/395

[52] U.S. Cl. 424/133.1; 530/387.3;
530/388.22; 424/143.1

[58] Field of Search 530/387.3, 388.22;
424/133.1, 143.1

[56] References Cited

U.S. PATENT DOCUMENTS

4,578,335	3/1986	Urdal et al.	530/351
4,816,397	3/1989	Boss et al.	435/68
4,816,565	3/1989	Honjo et al.	435/69.1
4,816,567	3/1989	Cabilly et al.	530/387
4,845,198	7/1989	Urdal et al.	530/387.3
4,867,973	9/1989	Goers et al.	
5,198,359	3/1993	Taniguchi et al.	435/252.3
5,225,539	7/1993	Winter	530/387.3

FOREIGN PATENT DOCUMENTS

0171496	2/1986	European Pat. Off.	C12N 15/00
0173494	3/1986	European Pat. Off.	C12N 15/00
0184187	6/1986	European Pat. Off.	C12N 15/00
0256654	7/1987	European Pat. Off.	
0239400	9/1987	European Pat. Off.	
0266663	6/1988	European Pat. Off.	C12N 15/00
2188941	10/1987	United Kingdom	C12N 5/00
86/05513	9/1986	WIPO	C12N 15/00
87/02671	5/1987	WIPO	C07H 15/12
89/01783	3/1989	WIPO	A61K 39/395

OTHER PUBLICATIONS

Riechmann et al. *Nature* vol. 332 24, Mar. 1988 p. 323.
 Foote, *Nova Acta Leopoldina* 1989, vol. 61 (269) 103.
 Amüt et al. *Science* vol. 233 1986 p. 747.
 Groves et al. vol. 6, 1987, p. 71.
 Better et al., "Escherichia coli Secretion of an Active Chimeric Antibody Fragment", *Science* 240:1041-1043 (1988).
 Bird et al., "Single-Chain Antigen-Binding Proteins", *Science* 242:423-426 (1988).
 Boulianne et al., "Production of functional chimeric mouse/human antibody," *Nature* 312:643-646 (1984).
 Carter et al., "Humanization of an anti-p185^{HER2} antibody for human cancer therapy," *Proc. Natl. Acad. Sci.* 89:4285-4289 (1992).
 Chothia, C. and A. M. Lesk, "Canonical Structures for the Hypervariable Regions of Immunoglobulins", *J. Mol. Biol.* 196:901-917 (1987).

Co et al., "Humanized antibodies for antiviral therapy," *Proc. Natl. Acad. Sci. USA* 88:2869-2873 (1991).

Co et al., "Chimeric and Humanized Antibodies with Specificity for the CD33 Antigen," *J. of Immunol.* 148(4):1149-1154 (1992).

Daugherty et al., "Polymerase chain reaction facilitates the cloning, CDR-grafting, and rapid expression of a murine monoclonal antibody directed against the CD18 component of leukocyte integrins," *Nuc. Acids Res.* 19:2471-2476 (1991).

Ellison et al., "The nucleotide sequence of a human immunoglobulin C(gamma)₁ gene", *Nucleic Acids Res.* 10:4071-(1982).

Farrar, J., "The biochemistry, biology, and role of interleukin-2 in the induction of cytotoxic T cell and antibody-forming B cell receptors," *Immunol. Rev.* 63:129-166 (1982).

Foote et al., "Antibody framework residues affecting the conformation of hypervariable loops," *J. Mol. Biol.* 224:487-499 (1992).

Gorman et al., "Reshaping a therapeutic CD4 antibody," *Proc. Natl. Acad. Sci.* 88:4181-4185 (1991).

Greene et al., "Growth of Human T Lymphocytes: An Analysis of Interleukin 2 and Its Cellular receptor", in *Progress in Hematology XIV*, E. Brown, ed., Grunc and Statton, New York (1986) pp. 283-301.

Hale et al., "Remission Induction in Non-Hodgkin Lymphoma with Reshaped Human Monoclonal Antibody CAMPATH-1H", *Lancet* Dec. 17, 1988, pp. 1394-1399.

Hieter et al., "Cloned Human and Mouse Kappa Immunoglobulin Constant and J Region Genes Conserve Homology in Functional Segments", *Cell* 22:197-207 (1980).

(List continued on next page.)

Primary Examiner—Lila Feisce

Attorney, Agent, or Firm—Townsend and Townsend and Crew LLP

[57]

ABSTRACT

Novel methods for producing, and compositions of humanized immunoglobulins having one or more complementarity determining regions (CDR's) and possible additional amino acids from a donor immunoglobulin and a framework region from an accepting human immunoglobulin are provided. Each humanized immunoglobulin chain will usually comprise, in addition to the CDR's, amino acids from the donor immunoglobulin framework that are, e.g., capable of interacting with the CDR's to effect binding affinity, such as one or more amino acids which are immediately adjacent to a CDR in the donor immunoglobulin or those within about 3 Å as predicted by molecular modeling. The heavy and light chains may each be designed by using any one or all of various position criteria. When combined into an intact antibody, the humanized immunoglobulins of the present invention will be substantially non-immunogenic in humans and retain substantially the same affinity as the donor immunoglobulin to the antigen, such as a protein or other compound containing an epitope.